REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the Official Action dated 11 August 2004. Responsive to the rejection made in the Official Action, Claim 1 – 5 have been amended to clarify the combination of elements which form the invention of the subject Patent Application.

In the Official Action, the Examiner rejected Claims 1 – 6, as originally filed, under 35 U.S.C. § 102(b) as being anticipated by Perrier, et al. (U.S. Patent #5,123,918). The Examiner stated that Perrier disclosed a tri-leaflet heart valve comprising: an annular valve base with an inner surface defining a central orifice through which a blood flow moves from an upstream side to a downstream side; three protruding hinges (16, 20) formed on the inner surface of the annular base, each hinge comprising a convex downstream face connected to a convex upstream face by a convex ridge and a pair of concave sockets on opposite sides of the hinge; and three leaflets arranged between adjacent hinges, each leaflet (106) being provided with a pair of round pivots (108) respectively mounted inside the concave sockets of the hinges and thus allowing the leaflets to rotate freely with in the annular valve base; when the leaflets are subject to a positive pressure from the blood flow, the leaflets are fully opened to allow the blood to flow through the central orifice, and when the leaflets are subject to a negative pressure, the leaflets are closed to occlude the blood flow.

Before discussing the reference relied upon by the Examiner, it is believed beneficial to first briefly review the structure of the invention of the subject Patent Application, as now claimed. The invention of the subject Patent Application is directed to a tri-leaflet heart valve comprised of an annular valve base, three protruding hinges and three leaflets. The annular valve base has an inner surface that defines a central orifice through which a blood flow moves from an upsteam side to a downstream side. The three protruding hinges are formed on the inner surface of the annular valve base and equally spaced along the inner surface of the annular valve base. Each hinge comprises a convex downstream face connected to a convex upstream face by a curved ridge and a pair of concave sockets on opposite sides of the hinge. The three leaflets are arranged between adjacent hinges. Each leaflet has an arcuate contour and is provided with a pair of round pivots respectively mounted inside the concave sockets of the hinges. Each of leaflets is respectively suspended between a corresponding pair of concave sockets and is freely rotatable within the annular valve base. When the leaflets are subject to a positive pressure from the blood flow, the leaflets are fully opened to allow the blood to flow through the central orifice, and when the leaflets are subject to a negative pressure, the leaflets are closed to occlude the blood flow.

In contradistinction, the Perrier reference discloses a heart valve with at least two flaps. The flaps are guided and retained by means of arcs 20 and 40. Each flap has two arcs 20 for guiding and retaining the trailing edge 7 of the flap, and two arcs 40/140 to

guide and retain the leading edge of each flap. The arcs 20, 40 are seen as arcuate projections that extend into the central flow path, as shown in Fig. 4. When the flap is in the open position, the leading edge 6 of the flap abuts to a first portion 19 of arc 40. When the flap is in the closed position, a second portion 21 extends to a point which is in contact with the inside face of the flap. The arcs 140 are disclosed as a projection 118 that includes an outer retaining segment 121. This outer segment is specifically disclosed as "guiding and retaining the leading edge 106 of the flap 102" and that it "extends into the flow path, as shown in Fig. 7, when the flap is in its open position". Any structure that projects into the central flow path can cause unwanted wakes and turbulence of the blood flow. The arcs 140 that guide and support the flaps are in addition to a socket structure that includes an arc 120 bordering a depression 115 with arcs 120 defined by the curved and convex downstream segments 116 and curved and convex upstream segments 117. The supporting arcs are necessary "in order to avoid the flap escaping from its retaining means", Col. 6, Lines 28-36 and Col. 9, Lines 50-57. In addition, the flaps, as best shown in Figures 16, 17 and 18 of Perrier, are predominately flat with bent corners 160. These corners serve as a stop against the annular base for the flaps in their open position. Thus, there is a flow path between the flaps and the annular base. For a heart valve with three flaps, four streams of blood flow are formed, which is susceptible to separation at the boundary layer and turbulence, causing damage to the blood cells and formation of thrombosis.

Whereas, in the invention of the Subject Application, each leaflet has an arcuate contour and each of the leaflets is respectively suspended between a corresponding pair of concave sockets. The arcuate contour of the leaflets of the invention of the subject Application provides a seal that prevents flow between the leaflets and the annular base, as defined in Amended Claim 5. Also, the structure of the pivots 40 and concave sockets 35 obviate the need for other structures to support the leaflets, unlike the system of Perrier, et al. Perrier, et al. neither discloses nor suggests arcuately shaped leaflets or a pivot and socket structure that enables the leaflets to be suspended between the sockets. Therefore, as the reference fails to disclose each and every element of the claimed invention, as now claimed, it cannot anticipate that invention. Further, as the reference fails to suggest such a combination of elements, it cannot make obvious that invention either.

As now defined in Claim 4 of the Subject Application, the fan-shaped leaflet has the bottom edge forming a tight seal with a corresponding upstream recess on the inner surface of the annular valve base when the leaflets are closed. The tight seal between the bottom edge of the leaflet and the upstream recess on the inner surface of the annular valve base, when in the closed position, is assisted by a cantilevered effect produced by the pressure on a lever arm of the larger portion of the leaflets. The lever arm multiplies the sealing force of the bottom edge of the leaflet against the upstream recess. In the Perrier reference, the seal is located on an upper surface of the downstream located lip 80/projection 118. The sealing force on the flaps in Perrier is equal to the back pressure

of the upstream blood, and there is no force multiplying effect. Therefore, Perrier teaches away from the structure of the invention of the subject Patent Application. As the reference fails to disclose the structure defined in Claim 4, it cannot anticipate that invention. Additionally, as the reference fails to suggest the claimed combination of elements and in fact teaches away from that combination, it cannot make obvious that invention either. Still further, the remaining Dependent Claims are believed to each be patentably distinct, but are at least patentably distinct for the same reasons as Claim 1.

It is now believed that the subject Patent Application is in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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